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*Amneal Pharmaceuticals, LLC*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

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SHIRE LLC, et al. )  
 )  
 Plaintiffs, )  
 )  
 v. ) Civil Action No. 2:11-cv-03781-SRC-MAS  
 ) (CONSOLIDATED)  
 )  
 AMNEAL PHARMACEUTICALS, LLC et ) MOTION DATE: April 16, 2012  
al., )  
 ) FILED UNDER SEAL  
 Defendants. )

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**AMNEAL'S BRIEF IN OPPOSITION TO SHIRE'S MOTION FOR LEAVE  
TO FILE AMENDED COMPLAINTS**

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## I. Summary of Argument

Plaintiffs Shire LLC and Shire Development Inc. (collectively “Shire”) have *no* legitimate basis for amending their Complaint to add an 18<sup>th</sup> patent, *no* answer to the Federal Circuit’s recent decision rejecting an argument identical to their own, and *no* excuse for delaying over seven months to raise this issue for the first time.



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<sup>1</sup> Defendants Actavis Elizabeth LLC and Actavis, Inc., (“Actavis”), Roxane Laboratories, Inc. (“Roxane”), and Sandoz Inc. (“Sandoz”) requested clarification on the remaining aspects of Shire’s Motion, *i.e.*, (i) substituting Shire Development Inc. for Shire Development LLC, (ii) adding Johnson Matthey Materials and Johnson Matthey Inc. as Defendants, and (iii) adding United States Patent Nos. 7,662,788 and 7,731,936 to the lawsuit. Amneal does not oppose these aspects of Shire’s Motion, so long as Shire abides by the representations made to the Defendants, which are highlighted in Defendants’ Clarification Brief filed on March 19, 2012. (D.I. 71).



Amneal *repeatedly* requested that Shire refrain from making this frivolous assertion, calling Shire's attention to the controlling Federal Circuit case law and the undisputed evidence of record. Shire ignored Amneal's requests, and proceeded to file its Motion—an action reflecting Shire's 'scorched earth' approach to litigating this 17 patent lawsuit. But the facts today are the same as they were over ten months ago when Shire was first put on notice of Amneal's ANDA. [REDACTED]

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<sup>2</sup> The jurisdictional basis for the artificial act of infringement under 35 U.S.C. § 271(e)(2) is premised upon the filing of an ANDA. § 271(e)(2) merely confers case-or-controversy jurisdiction to address actual infringement, inducement of infringement, or contributory infringement under § 271(a), (b), or (c). *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365-66 (Fed. Cir. 2003).

## II. Background

The following is an overview of *all* relevant facts before this Court, notably absent from Shire's Motion. Included is a discussion of the relevant Hatch-Waxman statutory scheme, as well as the background to the Amneal lawsuit.

### A. The Hatch-Waxman Statutory Framework

The Food, Drug, and Cosmetics Act ("FDCA") sets forth the requirements for introducing pharmaceutical drugs into the United States market. Companies seeking to market a new brand name (*i.e.*, "innovator") drug must submit a New Drug Application ("NDA"). NDAs contain detailed information about the safety and efficacy of the drug, as well as a listing of all patents that claim the drug or method of using the drug. 21 U.S.C. § 355(b)(1)(G). The Food and Drug Administration ("FDA") publishes a list of these patents in an electronic database known as APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, commonly referred to as the "Orange Book."

The Drug Price Competition and Patent Term Restoration Act, usually referred to as the "Hatch-Waxman Act," authorizes the filing of an Abbreviated New Drug Application ("ANDA") by a manufacturer seeking to market a generic equivalent of an innovator drug. 21 U.S.C. § 355(j). The ANDA permits the generic manufacturer to rely on the safety and efficacy information submitted by the innovator with the NDA, so long as "bioequivalence" is established between the brand drug and the generic version. 21 C.F.R. § 320 *et seq.*

An ANDA applicant can make *one* of the following four certifications for each patent listed in the Orange Book for an innovator drug:

Paragraph I: that no patent information for the pioneer drug has been submitted to the FDA;

Paragraph II: that the patent has expired;

Paragraph III: that the patent will expire on a specific date; or

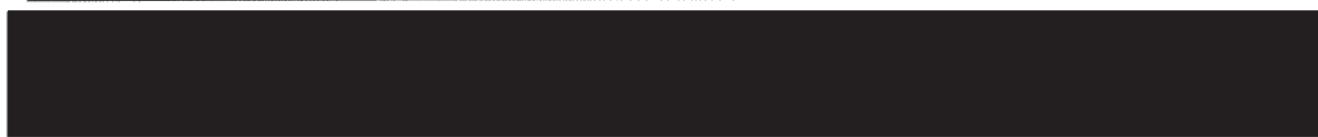
Paragraph IV: that the patent “is invalid or will not be infringed by the manufacture, use, or sale of the new drug” for which the ANDA applicant seeks approval (a “Paragraph-IV certification”).

21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV).

An applicant submitting a Paragraph-IV certification must give notice to “each owner of the patent that is the subject of the certification . . . and . . . the holder of the approved [NDA].”

21 U.S.C. § 355(j)(2)(B)(iii). Upon receiving this notice, a patent holder has 45 days to bring suit for patent infringement under 35 U.S.C. § 271(e)(2). 21 U.S.C. § 355(j)(5)(B)(iii). If a patent holder files a lawsuit, the FDA will not approve the ANDA until the court rules that the patent is not infringed, invalid, or until 30 months have passed since the receipt of the Paragraph-IV notice letter. *Id.*

The filing of a Paragraph-IV certification is considered to be a “highly artificial” act of patent infringement that gives rise to an action under 35 U.S.C. § 271(e)(2)(A). *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). Absent this statutory creation of infringement, no basis to assert jurisdiction exists. *Id.* Only a Paragraph-IV certification against the innovator drug patents listed in the Orange Book gives rise to an action under 35 U.S.C. § 271(e)(2)(A). *Eisai Co., Ltd. v. Mutual Pharm. Co.*, 2007 WL 4556958, at \*3 (D.N.J. Dec. 20, 2007) (Ackerman, J.) (relying on *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995)).



## B. The Amneal Lawsuit

### 1. Pre-Lawsuit Phase

On February 23, 2011, Amneal filed an ANDA with the FDA seeking approval to market 20-70 mg dosage strengths of lisdex capsules.<sup>4</sup> (Frueauf Decl., Ex. 1, AMVYV\_0000001-07).<sup>5</sup> Amneal's ANDA, designated as No. 202830 by the FDA, included a "Patent Certification" statement for each of the 16 Orange Book listed patents for lisdex.<sup>6</sup> (D.I. 15, ¶26; Frueauf Decl., Ex. 1, AMVYV\_0000091-102). [REDACTED]

[REDACTED]

There are three "Patent Use Codes" that are listed in the Orange Book; each corresponds to one or more of the Orange Book patents. (Frueauf Decl., Ex. 1, AMVYV\_0000110-124). These uses include:

Use 727 - For the Treatment of Attention Deficit Hyperactivity Disorder (ADHD),

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<sup>4</sup> Lisdex, or lisdexamphetamine dimesylate, is the active pharmaceutical ingredient in Vyvanse®. (D.I. 1, ¶8).

<sup>5</sup> "Frueauf Decl." refers to the *Declaration of Jeremiah B. Frueauf, in Support of Amneal's Brief in Opposition to Shire's Motion for Leave to File Amended Complaints* and attached Exhibits filed herewith.

<sup>6</sup> U.S. Patent Nos. 7,105,486, 7,223,735, 7,655,630, 7,659,253, 7,659,254, 7,662,787, 7,671,030, 7,671,031, 7,674,774, 7,678,770, 7,678,771, 7,687,466, 7,687,467, 7,700,561, 7,718,619, and 7,723,305. As Shire admits in its Brief, two additional patents were only recently listed in the Orange Book, U.S. Patent Nos. 7,662,788 and 7,713,936, after Amneal filed its ANDA. (Pls.' Br. 3; D.I. 1, ¶9).

[REDACTED]

Use 842 - Indicated for the Treatment of Attention-Deficit / Hyperactivity Disorder (ADHD), and

Use 1034 - Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in Adults.

(*Id.*) [REDACTED]

[REDACTED] (*Id.*). The FDA assigned these use codes based upon information provided by Shire.

Amneal notified Shire of its ANDA filing on May 19, 2011. (D.I. 1, ¶27; D.I. 15, ¶27;

Frueauf Decl., Ex. 2, 5/19/11 Notice Letter; *see also* 21 U.S.C. § 355(j)(2)(B). [REDACTED]

## 2. Pleading Phase

Shire filed a Complaint for patent infringement against Amneal on June 30, 2011. (D.I.

1).

Amneal answered Shire's Complaint on October 17, 2011, and included counterclaims (D.I. 15). As required by the Local Patent Rules, on this same date, Amneal also produced a copy of its ANDA [REDACTED] (Frueauf Decl., Ex. 3, 10/17/11 ltr. from J. Frueauf to E. Haug). Although Shire responded to Amneal's counterclaims on November 23, 2011 (D.I. 31), Shire never suggested during the initial pleadings phase that it had a basis to assert the '254 patent against Amneal. [REDACTED]

## 3. Initial Discovery

In late October 2011, the parties transitioned into case scheduling and discovery. All parties participated in a status conference before the Court on January 23, 2012. (D.I. 42). Again,

at no time did Shire suggest to Amneal, the Court, or any other party that it intended to allege infringement of the '254 patent against Amneal.

On February 6, 2012, Shire informed Amneal for the very first time of its intention to assert the '254 patent. (Frueauf Decl., Ex. 4, 2/6/12 ltr. from P. Fleming to D. Yonan). [REDACTED]

[REDACTED]

[REDACTED] Moreover, Amneal questioned Shire's pre-filing investigation, and *why* it took so long to identify this issue, which was raised over seven months after the Complaint had been filed, and over nine months after Shire was given Amneal's notice letter. (*Id.*) Amneal demanded a meet and confer in order to understand Shire's delay. (*Id.*)

The parties conferred on February 21, 2012, and although Shire acknowledged [REDACTED], it refused to withdraw its position. (D.I. 59). On February 28, 2012, the parties submitted a joint status letter to the Court advising of an impasse. (*Id.*). In this letter, Shire again refused to explain how Amneal could infringe the '254 patent and suggested it would "set forth its arguments" in an upcoming motion (*Id.* at 1).

Shire filed the Motion the day before the amendment of pleadings deadline. (D.I. 57). [REDACTED]

[REDACTED]

Ex. A at ¶¶105-106).

### **III. Argument**

A court can deny a plaintiff's leave to amend its complaint under Federal Rule of Civil Procedure 15(a)(2), where the amendment fails to state a cause of action, *i.e.*, is futile, or where

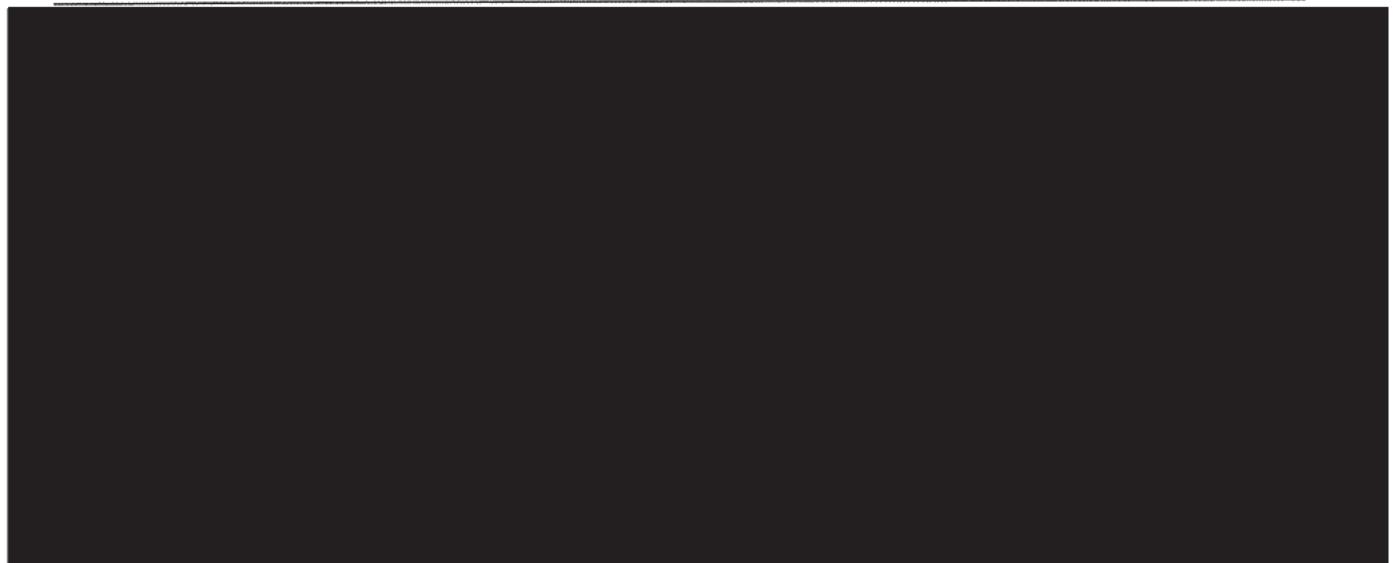
the plaintiff's delay in seeking the amendment is "undue, motivated by bad faith, or prejudicial to the opposing party." *Cureton v. Nat'l Collegiate Athletic Ass'n.*, 252 F.3d 267, 273 (3d Cir. 2001). An amendment is futile when the "the pleading as amended would not survive a motion to dismiss for failure to state a claim upon which relief could be granted." *Otsuka Pharm. Co., Ltd. v. Barr Labs., Inc.*, No. 07-1267 (MLC), 2008 WL 5120742, at \*4 (D.N.J Dec. 5, 2008) (Hughes, Mag.). In determining if an amendment is futile, the court applies "the same standard of legal sufficiency as would be applied to a 12(b)(6) motion." *Id.* (citing *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997)).<sup>8</sup>

Shire's Motion advances four reasons why its amendment should be granted: no undue delay, no bad faith or dilatory motive, no undue prejudice, and no futility. (Pls.' Br. 7-17). This Court need look no further than the futility of Shire's amendment, however, in order to dispose of this issue. Moreover, in view of the futility of this amendment, as well as Shire's bad faith motives and tactics, granting Shire's Motion will unduly prejudice Amneal.

#### **A. Adding the '254 Patent to the Amneal Lawsuit Is Futile**

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<sup>8</sup> Courts in this district have routinely denied parties' motions to amend when the pleadings, as amended, would not survive a motion to dismiss. See *Otsuka*, 2008 WL 5120742 at \*4 (denying motion to amend because plaintiff alleged an improper claim of willful infringement under 35 U.S.C. § 271(e)(2)); *Lascaris v. Griffin Investigations, Inc.*, No. 03-2172 (JAG), 2006 WL 54342, at \*3 (D.N.J. Jan. 10, 2006) (Greenway, J.) (denying motion to amend when plaintiff failed to state a valid claim under the statute being applied); *Wilson v. City of Newark*, No. 06-CV-5219 (DMC), 2008 WL 834398, at \*5-6 (D.N.J. Mar. 27, 2008) (Cavanaugh, J.) (denying motion to amend when plaintiff failed to allege a proper claim under the statue being applied and the amended complaint would not survive a motion to dismiss); *Coulter v. U.S. Dept. of Homeland Sec.*, No. 07-4894 (JAG), 2008 WL 4416454, at \*9 (D.N.J. Sept. 24, 2008) (Greenway, J.) (denying motion to amend when plaintiff alleged an improper tort claim against the government).



**1. Shire's Motion Lacks Any Evidence**

**2. No Cause of Action Exists Under § 271(e)(2)**

**3. No Cause of Action Exists Under § 271(a), (b), or (c)**



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## **B. Shire's Motion Was Not Filed in Good Faith**

The question of bad faith requires that the court focus on the moving party's motives for not amending earlier, and delay can be evidence of bad faith justifying denial of leave to amend. *Adams v. Gould, Inc.*, 739 F.2d 858, 868 (3d Cir. 1984). Further, “[i]f the court finds bad faith, the amendment should be denied, without regard to the issue of prejudice.” *Honeywell Int'l Inc. v. Raytheon Co.*, No. 08-3952 (SRC)(MAS), 2009 WL 2392884, at \*2 (D.N.J. Aug. 3, 2009) (Shipp, Mag.).

Shire asserts that no delay or bad faith exists, because it needed to “diligently” investigate infringement of the '254 patent first, which included a review of Amneal's ANDA. (Pls.' Br. 8-9). Shire, however, had Amneal's positions as early as May 20, 2011, when it received Amneal's notice letter. (D.I. 1, ¶27; D.I. 15, ¶27; Frueauf Decl., Ex. 2, 5/19/11 Notice Letter). Shire also received Amneal's ANDA on October 18, 2011, which is over five months before its Motion was filed. Shire's decision not to act on this information when it first had the opportunity to do so, [REDACTED]

[REDACTED] is symptomatic of bad faith.

[REDACTED]

These last minute efforts reflect a more troubling pattern. *See Phillips v. Borough of Keyport*, 179 F.R.D. 140, 149 (D.N.J. 1998) (Wolfson, Mag.) (stating that “[c]ourts will deny a motion to amend where the movant’s unexplained delay suggests bad faith or tactical design”). They represent tactical efforts by Shire to add as many patents as possible to this lawsuit, without regard to the actual merits. Thus, contrary to Shire’s bald assertion, “[t]he present situation is completely []like situations where a court has found bad faith.” (Pls.’ Br. 9 (citing *Wimm v. Jack Eckard Corp.*, 3 F.3d 137, 139 (5th Cir. 1993) (affirming district court’s finding that motion for leave to amend was filed in bad faith and with dilatory motive where movants had “ample opportunity to investigate their claims”))).<sup>14</sup>

### C. Undue Delay Is Present

Delay, where present, becomes undue when the moving party had previous opportunities to amend a complaint. *Cureton*, 252 F.3d at 273. The measure of whether delay is undue is based on a moving party’s reasons for not moving to amend sooner. *Id.* Here, Shire cannot explain *why*

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<sup>14</sup> *Wimm* cites to a number of additional Fifth Circuit Court of Appeals decisions that are informative to this issue. In each, the court denied a motion to amend on bad faith or where the facts for amendment were available at the time the movant filed its complaint. *See Wimm*, 3 F.3d at 141 (quoting *Dussouy v. Gulf Coast Inv. Corp.*, 660 F.2d 594, 599 (5th Cir. 1981) (“[[A] party’s] awareness of facts and failure to include them in the complaint might give rise to the inference that the [party] was engaging in tactical maneuvers to force the court to consider various theories *seriatim*.”); citing *Mitsubishi Aircraft Int’l, Inc. v. Brady*, 780 F.2d 1199, 1203 (5th Cir. 1986) (“stating that failure to urge a claim which is ‘usually apparent at the outset of a case . . . strongly suggests either a lack of diligence . . . or lack of sincerity’”); *Layfield v. Bill Heard Chevrolet Co.*, 607 F.2d 1097, 1099 (5th Cir. 1979) (“upholding denial of leave to amend, although bad faith and dilatory motive not found, where ‘all of the facts relevant to the proposed amendment were known to the [movant] at the time she filed her original complaint’”).

it did not alert Amneal, or the Court, of its proposed amendment any sooner, especially since it asserted the '254 patent against the other defendants over eight months ago—in June 2011.

Shire's delay started after it received Amneal's May 19, 2011 notice letter. (D.I. 1, ¶27; D.I. 15, ¶27; Frueauf Decl., Ex. 2, 5/19/11 Notice Letter). Shire did *nothing* between this time, and February 6, 2012, when it first indicated its intention to assert the '254 patent against Amneal. (Frueauf Decl., Ex. 4, 2/6/12 ltr. from P. Fleming to D. Yonan). If Shire had *any* legitimate basis for asserting the '254 patent, it would have alerted Amneal at the first available opportunity, not over ten months after it received Amneal's letter, and eight months after it filed its first Complaint. Moreover, there is *no explanation* why Shire wants to assert the '254 patent today, [REDACTED]

[REDACTED]  
It is also irrelevant that Shire's Motion was filed before the deadline to amend pleadings. Filing its Motion before an agreed-upon deadline to amend the pleadings does not excuse the most important fact to this Motion—[REDACTED]

#### **D. Amneal Will Be Prejudiced if Shire's Motion Is Granted**

While the Third Circuit Court of Appeals regards “prejudice to the nonmoving party as the ‘touchstone for the denial of the amendment,’” denial of leave to amend does not turn on the presence or absence of prejudice. *Coppa ex rel. Coppa v. Lajka*, Civ. A. 97-2054AET, 1997 WL 33550160, at \*2 (D.N.J. Dec. 16, 1997) (Hughes, J.) (quoting *Bechtel v. Robinson*, 886 F.2d 644, 652 (3d Cir. 1989)). [REDACTED]

[REDACTED]  
[REDACTED] For this reason alone, Shire's Motion should be denied.

#### IV. Conclusion

Shire's Motion should be denied. Not only is Shire's Motion futile because it fails to state any cause of action, let alone a claim upon which relief can be granted, but it also is grounded in bad faith and undue delay, in view of its failure to diligently pursue the '254 patent. Allowing Shire to proceed with asserting the '254 patent under these circumstances will prejudice Amneal, and Shire's tactics should not be permitted.

Respectfully submitted,

Dated: April 2, 2012

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## CERTIFICATE OF SERVICE

This is to certify that on April 2, 2012, a true and correct copy of: 1) Amneal's Brief in Opposition to Shire's Motion for Leave to File Amended Complaints; 2) Declaration of Jeremiah B. Frueauf in Support of Amneal's Brief in Opposition to Shire's Motion for Leave to File Amended Complaints and Exhibits 1-6; 3) Notice of Motion to Seal Materials; 4) Declaration of Jeremiah B. Frueauf in Support of Notice of Motion to Seal Materials; and 5) Proposed Order to Seal Materials were caused to be served by electronic mail on the following counsel of record:

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